K090778

Section 5: 510(k) Summary

APR 2 8 2009

The safety and effectiveness of MTA Protective Sheet is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

Sponsor: Xylos Corporation
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Langhorne, PA 19047

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Date of Submission: March 20, 2009

Proprietary Name: MTA™ Protective Sheet

Common Name: Surgical Mesh

Regulatory Class: Class II

Product Codes: FTM

Predicate Device(s): XYLOS® Surgical Mesh, K081882
MAST Biosurgery Ortho-Wrap™ Bioresorbable Sheet, K072190
(Ortho-Wrap™ is a Trademark of MAST Biosurgery, Inc.)

Device Description:

MTA Protective Sheet is composed of microbial-derived cellulose. The non-resorbable surgical mesh is used for the management and protection of tendon injuries. MTA Protective Sheet minimizes tissue attachment to the device in case of direct contact with the tissues. The implantable device is presented in a sterile double-pouched package for appropriate removal in preparation for surgery.

Indications for Use:

The MTA Protective Sheet is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. MTA Protective Sheet minimizes tissue attachment to the device in case of direct contact with the tissues. The device is indicated for open and endoscopic procedures. MTA Protective Sheet is intended for one-time use.

Technological Characteristics and Substantial Equivalence:

The MTA Protective Sheet is biocompatible since it is biologically and chemically identical to Securian Tissue Reinforcement Matrix previously cleared in K083823 and very similarly manufactured. In addition, the MTA Protective Sheet has similar indications for use to Securian Tissue Reinforcement Matrix as released in K083823.

Discussion of Performance Testing:

MTA Protective Sheet was subjected to various performance tests typical for its product code such as material property and suture pull out testing. Testing demonstrated its biomechanical equivalence to the predicate device, MAST Biosurgery Ortho-Wrap Bioresorbable Sheet. The MTA Protective Sheet met the test requirements, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

Conclusion:

MTA Protective Sheet is substantially equivalent to the previously cleared devices since it is:

1. Biologically and chemically identical and therefore has equivalent biocompatibility to the Securian Tissue Reinforcement as previously released in K083823.
2. Biomechanically equivalent as demonstrated via the above bench performance testing to MAST Biosurgery Ortho-Wrap Bioresorbable Sheet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2009

Xylos Corporation
% Ms. Joyce Elkins
Director Regulatory Affairs
and Quality Assurance
838 Town Center Drive
Langhorne, Pennsylvania 19047

Re: K090778
Trade/Device Name: MTA Protective Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: March 20, 2009
Received: March 23, 2009

Dear Ms. Elkins:

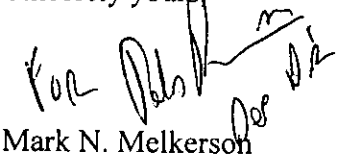
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090778

Device Name: MTA Protective Sheet

Indications For Use:

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Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090778